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Attorneys for Plaintiffs
VERINATA HEALTH, INC.

and

THE BOARD OF TRUSTEES
OF THE LELAND
STANFORD JUNIOR
UNIVERSITY

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

VERINATA HEALTH, INC.,

and

THE BOARD OF TRUSTEES OF THE
LELAND STANFORD JUNIOR
UNIVERSITY,

Plaintiffs,

v.

ARIOSIA DIAGNOSTICS, INC.,

and

LABORATORY CORPORATION OF
AMERICA HOLDINGS,

Defendants.

FILED
2012 OCT 25 A 9 11

RICHARD W. WIEKING
CLERK, U.S. DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

JSC

Case No.

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5501

**COMPLAINT FOR PATENT
INFRINGEMENT**

JURY TRIAL DEMANDED

**COMPLAINT
DEMAND FOR JURY TRIAL**

Case No.

1 Plaintiffs Verinata Health, Inc. ("Verinata") and The Board Of Trustees Of The
2 Leland Stanford Junior University ("Stanford"), for their complaint against Defendants Ariosa
3 Diagnostics, Inc. ("Ariosa") and Laboratory Corporation of America Holdings ("LabCorp")
4 (collectively "Defendants"), allege as follows:

5 **NATURE OF THIS ACTION**

6 1. This action arises under 28 U.S.C. §§ 1331 and the United States Patent
7 Act, 35 U.S.C. § 100 *et seq.*

8 2. Verinata and Stanford bring this action to halt Defendants' infringement of
9 Verinata's rights under the Patent Laws of the United States, 35 U.S.C. § 1, *et. seq.*, which rights
10 arise under U.S. Patent Nos. 8,296,076 (the "'076 patent").

11 **PARTIES**

12 3. Verinata is a corporation organized and existing under the laws of the State
13 of Delaware, with its principal place of business at 800 Saginaw Drive, Redwood City, California
14 94063. Verinata was formerly known as Artemis Health, Inc. ("Artemis"). Verinata's research
15 and clinical facilities are located in Redwood City, California. Verinata is also an exclusive
16 licensee of the '076 patent in the field of genetic analysis by nucleic acid sequencing.

17 4. Stanford is a trust possessing corporate powers that is organized under the
18 laws of California, with a principal place of business at the Office of the President, Building 10
19 Main Quad, Stanford, California 94305. Stanford is the patent owner and licensor for the '076
20 patent and is joined in the infringement action for this patent because it is a necessary party.

21 5. On information and belief, Ariosa is a company organized and existing
22 under the laws of Delaware, with its principal place of business at 5945 Optical Court, San Jose,
23 California 95138.

24 6. On information and belief, LabCorp is a company organized and existing
25 under the law of Delaware, with its principal place of business at 358 South Main Street,
26 Burlington, North Carolina 27215.

27 7. Defendants have, and have had, continuous and systematic contacts with
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the State of California, including this District. For instance, Ariosa has acknowledged in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, Civil Action No. 11-03691 (N.D. Cal. Dec. 19, 2011) that it “currently is, and has been, using the Aria Test in this District to conduct clinical studies in order to validate the performance of the test in detection of fetal chromosome abnormalities.” Likewise, LabCorp maintains numerous laboratory facilities in this district. On information and belief, Defendants have purposefully directed a broad range of business activities at this District, including among other things research, sales, blood collection and processing, and related services. On information and belief, residents of this District have used services sold by or from Defendants.

JURISDICTION AND VENUE

8. This action arises under the Patent Laws of the United States of America, 35 U.S.C. § 1 *et seq.* This Court has federal question jurisdiction under 28 U.S.C. § 1331 and 28 U.S.C. § 1338(a) because this is a civil action arising under the Patent Act.

9. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c) because a substantial part of the events giving rise to Verinata and Stanford’s claim occurred in this District and because Defendants are subject to personal jurisdiction in this District.

INTRA-DISTRICT ASSIGNMENT

10. Pursuant to Civil Local Rules 3-5(b) and 3-2(c), because this action is an intellectual property action, it is properly assigned to any of the divisions in this District.

BACKGROUND

11. Since its founding, Verinata’s activities have focused on developing and offering non-invasive tests for early identification of fetal chromosomal abnormalities using its proprietary technologies. In early 2012, Verinata began offering such a test, the verifi® prenatal test, on a commercial basis. The verifi® prenatal test employs novel techniques to analyze cell-free DNA circulating in the blood of a pregnant woman by DNA sequencing in order to determine whether a fetus is at risk of having an abnormal number of chromosomes (sometimes referred to as “aneuploidy”).

12. In or around May 2012, Ariosa and LabCorp began offering a commercial non-invasive prenatal test for Down syndrome, which they referred to by the trade name Harmony™ Prenatal Test. As Ariosa stated in a press release dated May 7, 2012, “[t]he Harmony Prenatal Test, which detects common fetal trisomies such as Trisomy 21 (associated with Down syndrome), will be offered through LabCorp and will be available at its 1,000+ patient service centers.”

13. The press release goes on to explain that the Harmony™ Prenatal Test “is performed using a simple maternal blood draw taken at a doctor’s office or patient service center.” Technical literature describing the technology underlying the Harmony™ Prenatal Test (which Ariosa identifies in a section of its website entitled “ABOUT THE SCIENCE”) explains that the method involves *inter alia* sequencing predefined subsequences of maternal and fetal DNA present in the maternal blood draw. *See, e.g.*, Sparks, A.B., Struble, C.A., Wang, E.T., Song, K., Oliphant, A., Non-invasive Prenatal Detection and Selective Analysis of Cell-free DNA Obtained from Maternal Blood: Evaluation for Trisomy 21 and Trisomy 18, *Am. J. Obstet. Gynecol.* (2012). In view of this description, on information and belief Defendants’ Harmony™ Prenatal Test infringes the ’076 patent directly and indirectly.

14. On information and belief, Defendants have and continue to perform the Harmony™ Prenatal Test on samples of maternal blood. Likewise, on information and belief, LabCorp has and continues to encourage Ariosa to perform the Harmony™ Prenatal Test, intending that Ariosa perform the test

15. On information and belief, LabCorp has and continues to supply to Ariosa material components of the Ariosa™ Prenatal Test having no substantial non-infringing use.

COUNT I

Infringement of U.S. Patent No. 8,296,076

16. Plaintiffs re-allege and incorporate by this reference the allegations contained in paragraphs 1 through 15 above as relevant to this count.

17. On October 23, 2012, the United States Patent and Trademark Office duly

1 and legally issued the '076 patent, entitled "Noninvasive Diagnosis of Fetal Aneuploidy By
2 Sequencing."

3 18. Stephen Quake, Ph.D., and Hei-Mun Christina Fan, Ph.D., are the sole and
4 true inventors of the '076 patent. By operation of law and as a result of written assignment
5 agreements, Stanford obtained the entire right, title, and interest to and in the '076 patent.

6 19. Pursuant to license agreements Verinata entered into with Stanford,
7 Verinata obtained an exclusive license to the '076 patent in the field of genetic analysis by
8 nucleic acid sequencing.

9 20. On information and belief, Defendants have and continue to directly
10 infringe the '076 patent by practicing one or more claims of the '076 patent by, including without
11 limitation, performing the Harmony™ Prenatal Test, and will continue to do so, unless and until
12 enjoined by this Court.

13 21. On information and belief, LabCorp has and continues to induce others to
14 infringe the '076 patent by, including without limitation, encouraging Ariosa to perform the
15 Harmony™ Prenatal Test, and will continue to do so, unless and until enjoined by this Court.

16 22. On information and belief, LabCorp has and continues to contributorily
17 infringe the '076 patent by, including without limitation, supplying to Ariosa material
18 components of the Harmony™ Prenatal Test having no substantial non-infringing use, and will
19 continue to do so, unless and until enjoined by this Court.

20 23. Defendants' infringement of the '076 patent has injured Plaintiffs in their
21 business and property rights. Plaintiffs are entitled to recovery monetary damages for such
22 injuries pursuant to 35 U.S.C. § 284 in an amount to be determined at trial.

23 24. Defendants' infringement of the '076 patent has caused irreparable harm to
24 Plaintiffs and will continue to cause such harm unless and until their infringing activities are
25 enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Verinata and Stanford pray for relief as follows:

- A. Judgment that Defendants have infringed, induced others to infringe, and/or contributorily infringed the '076 patent;
- B. An order permanently enjoining Defendants from further infringement of the '076 patent;
- C. An award of damages pursuant to 35 U.S.C. § 284;
- D. An order for an accounting of damages from Defendants' infringement;
- E. An award of enhanced damages, up to and including trebling of the damages awarded to Verinata and Stanford;
- F. An award to Verinata and Stanford of their costs and reasonable expenses to the fullest extent permitted by law;
- G. A declaration that this case is exceptional pursuant to 35 U.S.C. § 285, and an award of attorneys' fees and costs; and
- H. An award of such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b) and Civil Local Rule 3-6(a), Verinata and Stanford hereby demand a trial by jury on all issues so triable.

1 Dated: October 24, 2012

Respectfully submitted,

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6 Michele A. Gauger

7 By: 

8 Edward R. Reines
9 Attorneys for Plaintiffs
10 VERINATA HEALTH, INC.

11 and
12 THE BOARD OF TRUSTEES OF
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